## 510(K) SUMMARY

Submitter's Name: Mettler Electronics Corp.

Address:

1333 South Claudina Street

Anaheim, CA 92805

Telephone:

714-533-2221

**Contact:** 

Robert E. Fleming

Director, OA/RA

Date Prepared: March 26, 2002

#### **Device Name:**

a. TRADE NAME:

Sys\*Stim® 208/208A, Model ME 208/208A

MAY 3 0 2003

b. CLASSIFICATION NAME:

Powered Muscle Stimulator

c. COMMON NAME:

**Electrical Muscle Stimulator** 

### **Predicate Devices:**

a. TRADE NAME:

Chattanooga's Intelect LV110/LV120

AMREX' MS322/MS324

b. 510(k) Number:

K861248

Pre-amendment device

## **Description of Device:**

## Sys\*Stim 208, Model ME 208

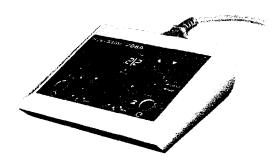
The microprocessor controlled Sys\*Stim 208 produces low volt current through one channel. The unit produces an asymmetrical electrically balanced waveform. There are three modes of operation: Pulse—1 to 80 Hz, Tetanize—Continuous Output, 80 Hz and Surge—80 Hz, On/Off times variable. The Sys\*Stim 208 is portable and beautifully designed. Up and down buttons control the timer while easy-to-use knobs allow you to select treatment parameters and adjust intensity. An optional accessory for the Sys\*Stim 208 is the Patient Termination Switch, which is connected to the jack located on back of the unit.



## SYS\*STIM <sup>®</sup> 208/208A, MODEL ME 208/208A 510(K) SUMMARY

## Sys\*Stim 208A, Model ME 208A

The microprocessor controlled Sys\*Stim 208A produces low volt current through two channels. The unit produces an asymmetrical electrically balanced waveform. There are four modes of operation: Pulse—1 to 80 Hz, Tetanize—Continuous Output, 80 Hz, Surge—80 Hz, On/Off times variable and Recip—80 Hz, output alternates between the two channels. The Sys\*Stim 208A is portable and beautifully designed. Up and down buttons control the timer while easy-to-use knobs allow you to select treatment parameters and adjust intensity. An optional accessory for the Sys\*Stim 208A is the Patient Termination Switch, which is connected to the jack located on back of the unit.



## **Device Intended Use Statement:**

510(k) Number:

Device Name: Sys\*Stim® 208/208A, Model ME 208/208A

#### Indications for use:

- 1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain.
- 2. Temporary relaxation of muscle spasm.
- 3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles.
- 4. Increase of blood flow in the treatment area.
- 5. Prevention or retardation of disuse atrophy in post-injury type conditions.
- 6. Muscle re-education.
- 7. Maintaining or increasing range of motion.

# SYS\*STIM <sup>®</sup> 208/208A, MODEL ME 208/208A 510(K) SUMMARY

Comparison of Technological Characteristics Between Sys\*Stim® 208/208A, Model ME 208/208A and Predicate Devices:

## **ME 208**

510 K#	К	K880235	Pre-amendment
Device Name	Sys∗Stim 208	LV-110	MS322
Manufacturer	Mettler Electronics	Chattanooga	Amrex-Zetron
Power Source	110 V AC, 60 Hz ±10%	120 V AC, 50/60 Hz	120 V AC, 60 Hz
Number Of Output Modes	3	3	3
Channel(S)	1	1	1
Synchronous	N/A	N/A	N/A
Reciprocal	N/A	N/A	N/A
Computerized	No	No	No
Software Provided	N/A	N/A	N/A
Constant Current	No	Not stated in the manual	Not stated in the manual
Constant Voltage	Yes	Not stated in the manual	Not stated in the manual
Max Output Current (mA)	184 mA peak ±20% into 500 Ω 72 mA peak ±20% into 2 KΩ 17 mA peak ±20% into 10		Not Stated in the manual
Max Output Voltage (V)	KΩ 92 V peak ±20% into 500 Ω 144 V peak ±20% into 2 KΩ 166 peak ±20% into 10 KΩ		110 V peak into 1K ohm load 28 V peak into 100 ohm load
Waveforms & Channels	·	•	•
All Channels	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC
Output Displays	No	No	No
Channel Isolation	In this system all the outputs are isolated from each other, they have their own amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is the microprocessor & the power supply.		Not Stated in the manual
Line Current Isolation	AC power supply is converted to DC Power supply through transformer. Hence there is an insulation of mains from circuitry. From circuitry to output again there is insulation through the transformer, there by double separation between mains and the human body.	Not Stated in the manual	Not Stated in the manual
Automatic Overload Trip	No	Not Stated in the manual	Not Stated in the manual
Automatic Over Current Trip	No	Not Stated in the manual	Not Stated in the manual
Current/Voltage Level	No	Not Stated in the manual	Not Stated in the manual

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Automatic No Load Trip	No	No	No
Automatic Shut-Off	Yes	Yes	Yes
Patient Override	Yes	Optional	Optional
Control Method	Remote stop	Remote stop	Remote stop
Max Leakage Current (μA)			
Normal	<100	Not Stated in the manual	<50
Single Fault	<300	Not Stated in the manual	<50
Indicator Display			
Unit Functioning	Yes	Yes	Yes
Low Battery Indicator	N/A	N/A	N/A
Standards			
UL 544	No	No	Yes
UL 2601-1-UL	No	No	No
CUL	No	No	No
CSA C22.2 NO 601.1-M90	No	No	No
IEC60601-2-10	No	No	No
EN-55011 (CISPR-11)	No	No	No
MDD 93/42/EEC, Annex II	No	No	No
•			
Compliance with 21 CFR 898	Yes	Yes	Yes
Timer Settings	0-60 minutes ±5%	0-30 minutes	0- 30 minutes
Automatic Shut Off	Yes	Yes	Yes
Weight (lbs.)	2.25	3	3
DIMENSIONS (in.)			
H x W x L	2.5 (H) x 6 (D) x 8 (L)	8 (D) x 5.2 (W) x 6.5 (H)	7.5 (D) x 7.25 (W) x 4.75 (H)
Housing Materials	ABS Plastic	Not stated in the manual	Not stated in the manual
Construction	Injection Molded	Not stated in the manual	Not stated in the manual
III. Alternating Current			
Туре	Biphasic	Biphasic	Alternating
Shape	Rectangular	Rectangular	Rectangular
Symmetry	Asymmetrical	Asymmetrical	Asymmetrical
Net Charge	Zero	Zero	Zero
Method	Balanced Waveform	Balanced Waveform	Balanced Waveform
Phase Duration Range	+ Phase = 200 µs ±10%	200 μs at 50% V max.	200 μs at 50% V max.
-	- Phase = 4 x + Phase ±10%		·
Interphase Interval	N/A	N/A	N/A
Frequency Range	1-80 Hz ±10%	1-80 Hz	1-80 Hz
Tetanize	80 Hz ±10%	80 Hz	80 Hz
Maximum Current Density	0.132 mA/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
Maximum Phase Charge (u Coulombs)	56 μC ±10% into a 100 ohm load	56 μC into a 100 ohm load	56 μC into a 100 ohm load

## SYS\*STIM ® 208/208A, MODEL ME 208/208A (03)017 510(K) SUMMARY

	010(11) 0011		
500 OHMS	33.5 ±10%	Not stated in the manual	Not stated in the manual
2K OHMS	13.1 ±10%	Not stated in the manual	Not stated in the manual
10K OHMS	3.4 ±10%	Not stated in the manual	Not stated in the manual
Formula	q = 1 x t	Not stated in the manual	Not stated in the manual

Maximum Power Density 0.012 W/cm² @ 500 Ω Not stated in the manual Not stated in the manual

#### **Amplitude Modulation Options**

Surge			
Frequency	80 Hz ±10%	80 Hz	80 H
A T.	0.0754-0.75	1400/ 0.0754- 0.75	0.070

 On Times
 0.375 to 3.75 seconds ±10% 0.375 to 3.75 seconds
 0.375 to 3.75 seconds

 Off Times
 0.375 to 3.75 seconds ±10% 0.375 to 3.75 seconds
 0.375 to 3.75 seconds

**Modulation Options** 

a) May Be Selected N/A N/A N/A Independently Or

Together
b) Simultaneously For

b) Simultaneously For N/A N/A N/A

Each Channel Pair
c) Independent Controls

c) Independent Controls N/A N/A N/A For Each Channel

Note 1: The Current density and Power density have been calculated using Average Current.

Average Current = (Pulse Width / Pulse Frequency ) • Peak Current

where Pulse Width and Pulse Frequency is in microseconds

Pulse Width = 182 microseconds @ 500 Ohms, Observed on CRO

Pulse Frequency = 12500 microseconds (80 Hz - Maximum Frequency)

charge Phase Charge = Pulse Width x Current (peak to peak)

equation for maximum current Current Density = (Pulse On period / Total Pulse period) x (Voltage /

density resistance)

equation for Power Density Power Density = Current Density x Output Voltage

## SYS\*STIM <sup>®</sup> 208/208A, MODEL ME 208/208A 510(K) SUMMARY

K031017

## **ME 208A**

510 K# Device Name	K Sys∗Stim 208A	K880235 LV-120	Pre-amendment MS324
Manufacturer	Mettler Electronics	Chattanooga	Amrex-Zetron
Power Source	110 V AC, 60 Hz ±10%	120 V AC, 50/60 Hz	120 V AC, 60 Hz
Number Of Output Modes	4	4	4
Channel(S)	2	2	2
Synchronous	Yes	Yes	Yes
Reciprocal	Yes	Yes	Yes
Computerized	No	No	No
Software Provided	N/A	N/A	N/A
Constant Current	No	Not stated in the manual	Not stated in the manual
Constant Voltage	Yes	Not stated in the manual	Not stated in the manual
Max Output Current (mA)	184 mA peak ±20% into 500 $\Omega$ 72 mA peak ±20% into 2 K $\Omega$ 17 mA peak ±20% into 10 K $\Omega$		Not Stated in the manual
Max Output Voltage (V)	92 V peak ±20% into 500 Ω 144 V peak ±20% into 2 ΚΩ		110 V peak into 1K ohm load
Maria de maria de Otras de A	166 peak ±20% into 10 KΩ	28 v peak into 100 onm load	28 V peak into 100 ohm load
Waveforms & Channels	A		
All Channels	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC
Output Displays	No	No	No
Channel Isolation	In this system all the outputs are isolated from each other, they have their own amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is the microprocessor & the power supply.		Not Stated in the manual
Line Current Isolation	AC power supply is converted to DC Power supply through transformer. Hence there is an insulation of mains from circuitry. From circuitry to output again there is insulation through the transformer, there by double separation between mains and the human body.	Not Stated in the manual	Not Stated in the manual
Automatic Overload Trip	No	Not Stated in the manual	Not Stated in the manual
Automatic Over Current Trip	No	Not Stated in the manual	Not Stated in the manual
Current/Voltage Level	No	Not Stated in the manual	Not Stated in the manual
Automatic No Load Trip	No	No	No
Automatic Shut-Off	Yes	Yes	Yes

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Patlent Override		510(K) SUMMAI		
Max Leakage Current (μA)   Normal   < 100   Not Stated in the manual   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50   < 50	Patient Override	Yes	Optional	Optional
Normal	Control Method	Remote stop	Remote stop	Remote stop
Single Fault	Max Leakage Current (μA)			- Allege -
Indicator Display	Normal	<100	Not Stated in the manual	<50
Unit Functioning         Yes         Yes         Yes           Low Battery Indicator         N/A         N/A         N/A           Standards         UL 544         No         No         No           UL 2601-1-JUL         No         No         No         No           CUL         No         No         No         No           CSA C22.2 NO 601.1-M90         No         No         No         No           EC60601-2-10         N/A         No         No         No           EN-55011 (CISPR-11)         N/A         No         No         No           MDD 93/42/EEC, Annex II         N/A         No         No         No           Compliance with 21 CFR 888         Yes         Yes         Yes           Timer Settings         O-60 minutes ±5%         O-30 minutes         0-30 minutes           Compliance with 21 CFR 888         Yes         Yes         Yes           Timer Settings         O-60 minutes ±5%         O-30 minutes         0-30 minutes           Compliance with 21 CFR 888         Yes         Yes         Yes           Weight (lbs.)         2.25         3         3         3           DIMENSIONS (in.)         H         Xys <th>Single Fault</th> <th>&lt;300</th> <th>Not Stated in the manual</th> <th>&lt;50</th>	Single Fault	<300	Not Stated in the manual	<50
Low Battery Indicator         N/A         N/A         N/A         N/A           Standards         UL 544         No         No         Yes           UL 2601-1-UL         No         No         No         No           CUL         No         No         No         No           CSA C22.2 NO 601.1-M90         No         No         No         No           IEC60601-2-10         N/A         No         No         No           EN-55011 (CISPR-11)         N/A         No         No           MDD 93/42/EEC, Annex II         N/A         No         No           Compliance with 21 CFR 896         Yes         Yes         Yes           Timer Settings         0-60 minutes ±5%         0-30 minutes         0-30 minutes           Automatic Shut Off         Yes         Yes         Yes           Veight (lbs.)         2.25         3         3           DIMENSIONS (in.)         H         Yes         Yes         Yes           H w x L         2.5 (H) x 6 (D) x 8 (L)         8 (D) x 5.2 (W) x 6.5 (H)         Not stated in the manual         Not stated in the manual           III. Afternating Current         Type         Biphasic         Biphasic         Alternating	Indicator Display			
Standards	Unit Functioning	Yes	Yes	Yes
UL 544	Low Battery Indicator	N/A	N/A	N/A
UL. 2801-1-UL	Standards			
CUL         No         No         No         No           CSA C22.2 NO 601.1-M90         No         No         No         No           IEC60601-2-10         N/A         No         No         No           EN-55011 (CISPR-11)         N/A         No         No           MDD 93/42/EEC, Annex II         N/A         No         No           Compliance with 21 CFR 898         Yes         Yes         Yes           Timer Settings         0-60 minutes ±5%         0-30 minutes         0-30 minutes           Automatic Shut Off         Yes         Yes         Yes           Automatic Shut Off         Yes         Yes         Yes           Weight (Ibs.)         2.25         3         3           DIMENSIONS (in.)         Hx         L         2.5 (H) x 6 (D) x 8 (L)         8 (D) x 5.2 (W) x 6.5 (H)         7.5 (D) x 7.25 (W) x 4.75 (H)           Housing Materials         ABS Plastic         Not stated in the manual         Not stated in the manual           Construction         Injection Molded         Not stated in the manual         Not stated in the manual           III. Alternating Current         Type         Biphasic         Biphasic         Alternating           Shape         Rectangular         Rect	UL 544	No	No	Yes
CSA C22.2 NO 601.1-M90   No   No   No   No   No   No   No     IEC60601-2-10   N/A   No   No   No   No   No   No     EN-55011 (CISPR-11)   N/A   No   No   No   No   No     MDD 93/42/EEC, Annex II   N/A   No   No   No     Compliance with 21 CFR 898   Yes   Yes   Yes   Yes    Timer Settings   0-60 minutes ±5%   0-30 minutes   0-30 minutes     Automatic Shut Off   Yes   Yes   Yes   Yes     Weight (lbs.)   2.25   3   3     DIMENSIONS (in.)   H x W x L   2.5 (H) x 6 (D) x 8 (L)   8 (D) x 5.2 (W) x 6.5 (H)   Not stated in the manual     Not stated in the manual   Not stated in the manual   Not stated in the manual     Not stated in the manual   Not stated in the manual     Not stated in the manual   Not stated in the manual     III. Alternating Current   Type   Biphasic   Biphasic   Alternating     Shape   Rectangular   Rectangular   Rectangular   Rectangular     Symmetry   Asymmetrical   Asymmetrical   Asymmetrical   Asymmetrical     Symmetry   Asymmetrical   Asymmetrical   Asymmetrical   Asymmetrical     Symmetry   Asymmetrical   Asymmetrical   Asymmetrical   Asymmetrical     Net Charge   Zero	UL 2601-1-UL	No	No	No
IEC60601-2-10	CUL	No	No	No
EN-55011 (CISPR-11)         N/A         No         No           MDD 93/42/EEC, Annex II         N/A         No         No           Compliance with 21 CFR 898         Yes         Yes         Yes           Timer Settings         0-60 minutes ±5%         0-30 minutes         0-30 minutes           Automatic Shut Off         Yes         Yes         Yes           Weight (lbs.)         2.25         3         3           DIMENSIONS (in.)         H x W x L         2.5 (H) x 6 (D) x 8 (L)         8 (D) x 5.2 (W) x 6.5 (H)         7.5 (D) x 7.25 (W) x 4.75 (H)           H x W x L         ABS Plastic         Not stated in the manual         Not stated in the manual         Not stated in the manual           Construction         Injection Molded         Not stated in the manual         Not stated in the manual         Not stated in the manual           III. Alternating Current         Type         Biphasic         Biphasic         Alternating         Rectangular         Rectangular         Rectangular         Asymmetrical	CSA C22.2 NO 601.1-M90	No	No	No
MDD 93/42/EEC, Annex II         N/A         No         No           Compliance with 21 CFR 898         Yes         Yes         Yes           Timer Settings         0-60 minutes ±5%         0-30 minutes         0-30 minutes           Automatic Shut Off         Yes         Yes         Yes           Weight (bs.)         2.25         3         3           DIMENSIONS (in.)         Hx Wx L         2.5 (H) x 6 (D) x 8 (L)         8 (D) x 5.2 (W) x 6.5 (H)         7.5 (D) x 7.25 (W) x 4.75 (H)           Housing Materials         ABS Plastic         Not stated in the manual         Not stated in the manual           Construction         Injection Molded         Not stated in the manual         Not stated in the manual           III. Alternating Current         Type         Biphasic         Alternating           Shape         Rectangular         Rectangular         Asymmetrical         Asymmetrical           Shape         Rectangular         Asymmetrical         Asymmetrical         Asymmetrical         Asymmetrical           Net Charge         Zero         Zero         Zero         Zero         Balanced Waveform         Balanced Waveform         Balanced Waveform         Balanced Waveform         Balanced Waveform         Balanced Waveform         Bolanced Waveform         Bolanced	IEC60601-2-10	N/A	No	No
Timer Settings	EN-55011 (CISPR-11)	N/A	No	No
Timer Settings	MDD 93/42/EEC, Annex II	N/A	No	No
Timer Settings				
Automatic Shut Off         Yes         Yes         Yes           Weight (lbs.)         2.25         3         3           DIMENSIONS (in.)           8 (D) x 5.2 (W) x 6.5 (H)         7.5 (D) x 7.25 (W) x 4.75 (H)           H x W x L         2.5 (H) x 6 (D) x 8 (L)         8 (D) x 5.2 (W) x 6.5 (H)         7.5 (D) x 7.25 (W) x 4.75 (H)           Housing Materials         ABS Plastic         Not stated in the manual         Not stated in the manual           Construction         Injection Molded         Not stated in the manual         Not stated in the manual           Ill. Alternating Current         Type         Biphasic         Alternating           Shape         Rectangular         Rectangular         Rectangular           Symmetry         Asymmetrical         Asymmetrical         Asymmetrical           Net Charge         Zero         Zero         Zero         Zero           Method         Balanced Waveform         Balanced Waveform         Balanced Waveform         Balanced Waveform         200 μs at 50% V max.         200 μs at 50% V max.           Phase Duration Range         1-80 Hz ±10%         1-80 Hz         1-80 Hz         1-80 Hz           Interphase Interval         N/A         N/A         N/A         N/A	Compliance with 21 CFR 898	Yes	Yes	Yes
Not stated in the manual   Not stated in the manual	Timer Settings	0-60 minutes ±5%	0-30 minutes	0- 30 minutes
DIMENSIONS (in.)         H x W x L       2.5 (H) x 6 (D) x 8 (L)       8 (D) x 5.2 (W) x 6.5 (H)       7.5 (D) x 7.25 (W) x 4.75 (H)         Housing Materials       ABS Plastic       Not stated in the manual       Not stated in the manual         Construction       Injection Molded       Not stated in the manual       Not stated in the manual         III. Alternating Current       Type       Biphasic       Alternating         Shape       Rectangular       Rectangular       Rectangular         Symmetry       Asymmetrical       Asymmetrical       Asymmetrical         Net Charge       Zero       Zero       Zero         Method       Balanced Waveform       Balanced Waveform       Balanced Waveform       Balanced Waveform         Phase Duration Range       + Phase = 200 µs ± 10%       200 µs at 50% V max.       200 µs at 50% V max.         - Phase = 4 x + Phase ± 10%       N/A       N/A       N/A         Interphase Interval       N/A       N/A       N/A       N/A         Tetanize       80 Hz ± 10%       80 Hz       80 Hz         Maximum Current Density       0.132 mA/cm² @ 500 $\Omega$ Not stated in the manual       Not stated in the manual         Maximum Phase Charge (u Coulombs)       56 $\mu$ C ±10% into a 100 ohm load load load <t< th=""><th>Automatic Shut Off</th><th>Yes</th><th>Yes</th><th>Yes</th></t<>	Automatic Shut Off	Yes	Yes	Yes
H x W x L Housing Materials2.5 (H) x 6 (D) x 8 (L) ABS Plastic8 (D) x 5.2 (W) x 6.5 (H) Not stated in the manual Not stated in the manual7.5 (D) x 7.25 (W) x 4.75 (H) Not stated in the manual Not stated in the manualIII. Alternating CurrentBiphasic ShapeBiphasic Rectangular Asymmetrical Asymmetr	Weight (lbs.)	2.25	3	3
Housing Materials       ABS Plastic       Not stated in the manual       Not stated in the manual       Not stated in the manual         Construction       Injection Molded       Not stated in the manual       Not stated in the manual         III. Alternating Current       Biphasic       Alternating         Type       Biphasic       Alternating         Shape       Rectangular       Rectangular         Symmetry       Asymmetrical       Asymmetrical         Net Charge       Zero       Zero       Zero         Method       Balanced Waveform       Balanced Waveform       Balanced Waveform       Balanced Waveform       Balanced Waveform       200 μs at 50% V max.         - Phase Duration Range       + Phase = 200 μs ±10%       200 μs at 50% V max.       200 μs at 50% V max.         - Phase = 10%       N/A       N/A       N/A         Interphase Interval       N/A       N/A       N/A         Frequency Range       1-80 Hz ±10%       1-80 Hz       1-80 Hz         Tetanize       80 Hz ±10%       80 Hz       Not stated in the manual         Maximum Phase Charge (u Coulombs)       56 μC ±10% into a 100 ohm load load       56 μC into a 100 ohm load load         500 OHMS       33.5 ±10%       Not stated in the manual       Not stated in the manual </th <th>DIMENSIONS (in.)</th> <th></th> <th></th> <th></th>	DIMENSIONS (in.)			
Construction       Injection Molded       Not stated in the manual       Not stated in the manual         III. Alternating Current       Type       Biphasic       Biphasic       Alternating         Shape       Rectangular       Rectangular       Rectangular         Symmetry       Asymmetrical       Asymmetrical       Asymmetrical         Net Charge       Zero       Zero       Zero         Method       Balanced Waveform       Balanced Waveform       Balanced Waveform         Phase Duration Range       + Phase = 200 μs ±10%       200 μs at 50% V max.       200 μs at 50% V max.         - Phase = 4 x + Phase ±10%       N/A       N/A       N/A         Interphase Interval       N/A       N/A       N/A         Frequency Range       1-80 Hz ±10%       1-80 Hz       1-80 Hz         Tetanize       80 Hz       80 Hz       80 Hz         Maximum Current Density       0.132 mA/cm² @ 500 Ω       Not stated in the manual       Not stated in the manual         Maximum Phase Charge (u Coulombs)       56 μC ±10% into a 100 ohm load load       56 μC into a 100 ohm load load       56 μC into a 100 ohm load load         500 OHMS       33.5 ±10%       Not stated in the manual       Not stated in the manual	HxWxL	2.5 (H) x 6 (D) x 8 (L)	8 (D) x 5.2 (W) x 6.5 (H)	7.5 (D) x 7.25 (W) x 4.75 (H)
III. Alternating Current   Type	Housing Materials	ABS Plastic	Not stated in the manual	Not stated in the manual
Type         Biphasic         Biphasic         Alternating           Shape         Rectangular         Rectangular         Rectangular           Symmetry         Asymmetrical         Asymmetrical         Asymmetrical           Net Charge         Zero         Zero         Zero           Method         Balanced Waveform         Balanced Waveform         Balanced Waveform           Phase Duration Range         + Phase = 200 μs ±10%         200 μs at 50% V max.         200 μs at 50% V max.           - Phase = 4 x + Phase ±10%         N/A         N/A         N/A           Interphase Interval         N/A         N/A         N/A           Frequency Range         1-80 Hz ±10%         1-80 Hz         1-80 Hz           Tetanize         80 Hz ±10%         80 Hz         80 Hz           Maximum Current Density         0.132 mA/cm² @ 500 Ω         Not stated in the manual         Not stated in the manual           Maximum Phase Charge (u Coulombs)         56 μC ±10% into a 100 ohm load load         56 μC into a 100 ohm load load         Not stated in the manual         Not stated in the manual	Construction	Injection Molded	Not stated in the manual	Not stated in the manual
ShapeRectangularRectangularRectangularSymmetryAsymmetricalAsymmetricalAsymmetricalNet ChargeZeroZeroZeroMethodBalanced WaveformBalanced WaveformBalanced WaveformPhase Duration Range+ Phase = $200 \mu s \pm 10\%$ - Phase = $4 x + Phase \pm 10\%$ $200 \mu s$ at $50\% V$ max. $200 \mu s$ at $50\% V$ max.Interphase IntervalN/AN/AN/AN/AFrequency Range $1-80 Hz \pm 10\%$ $1-80 Hz$ $1-80 Hz$ $1-80 Hz$ Tetanize $80 Hz \pm 10\%$ $80 Hz$ $80 Hz$ $80 Hz$ Maximum Current Density $0.132 \text{ mA/cm}^2 @ 500 \Omega$ Not stated in the manualNot stated in the manualMaximum Phase Charge (u Coulombs) - 500 OHMS $56 \mu C \pm 10\%$ into a $100 \text{ ohm}$ load load - Not stated in the manual $56 \mu C$ into a $100 \text{ ohm}$ load load - Not stated in the manual	III. Alternating Current			
Symmetry Net Charge Method Phase Duration RangeAsymmetrical ZeroAsymmetric	Туре	Biphasic	Biphasic	Alternating
Net Charge Method Phase Duration RangeZeroZeroZeroZeroPhase Duration Range $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 1000$ $\pm 10000$ $\pm 10000$ $\pm 10000$ $\pm 10000$ $\pm 10000$ $\pm 10000$ $\pm 10000$ <th>Shape</th> <th>Rectangular</th> <th>Rectangular</th> <th>Rectangular</th>	Shape	Rectangular	Rectangular	Rectangular
Method Phase Duration RangeBalanced Waveform + Phase = 200 μs ±10% - Phase = 4 x + Phase ±10%Balanced Waveform 	Symmetry	Asymmetrical	Asymmetrical	Asymmetrical
Phase Duration Range         + Phase = 200 μs ±10% - Phase ±10%         200 μs at 50% V max.         200 μs at 50% V max.           Interphase Interval         N/A         N/A         N/A           Frequency Range         1-80 Hz ±10%         1-80 Hz         1-80 Hz           Tetanize         80 Hz ±10%         80 Hz         80 Hz           Maximum Current Density         0.132 mA/cm² @ 500 Ω         Not stated in the manual         Not stated in the manual           Maximum Phase Charge (u Coulombs)         56 μC ±10% into a 100 ohm load load         56 μC into a 100 ohm load load         56 μC into a 100 ohm load load           500 OHMS         33.5 ±10%         Not stated in the manual         Not stated in the manual	_	Zero	Zero	Zero
Interphase Interval   N/A   N/A   N/A   N/A   N/A	Method	Balanced Waveform	Balanced Waveform	Balanced Waveform
Interphase IntervalN/AN/AN/AN/AFrequency Range1-80 Hz ±10%1-80 Hz1-80 HzTetanize80 Hz ±10%80 Hz80 HzMaximum Current Density0.132 mA/cm² @ 500 ΩNot stated in the manualNot stated in the manualMaximum Phase Charge (u Coulombs)56 μC ±10% into a 100 ohm load load56 μC into a 100 ohm load load500 OHMS33.5 ±10%Not stated in the manualNot stated in the manual	Phase Duration Range	+ Phase = 200 µs ±10%	200 μs at 50% V max.	200 μs at 50% V max.
Frequency Range1-80 Hz ±10%1-80 Hz1-80 HzTetanize80 Hz ±10%80 Hz80 HzMaximum Current Density0.132 mA/cm² @ 500 ΩNot stated in the manualNot stated in the manualMaximum Phase Charge (u Coulombs)56 μC ±10% into a 100 ohm load load56 μC into a 100 ohm load load56 μC into a 100 ohm load load500 OHMS33.5 ±10%Not stated in the manualNot stated in the manual		- Phase = 4 x + Phase ±10%	1	
Tetanize 80 Hz ±10% 80 Hz 80 Hz  Maximum Current Density 0.132 mA/cm² @ 500 Ω Not stated in the manual Not stated in the manual  Maximum Phase Charge (u Coulombs) 56 μC ±10% into a 100 ohm 56 μC into a 100 ohm load load Not stated in the manual Not stated in the manual	Interphase Interval	N/A	N/A	N/A
Maximum Phase Charge (u Coulombs)       56 μC ±10% into a 100 ohm load load       56 μC into a 100 ohm load load       56 μC into a 100 ohm load load       56 μC into a 100 ohm load load         500 OHMS       33.5 ±10%       Not stated in the manual       Not stated in the manual	Frequency Range	1-80 Hz ±10%	1-80 Hz	1-80 Hz
Maximum Phase Charge (u Coulombs)56 μC ±10% into a 100 ohm load56 μC into a 100 ohm load load56 μC into a 100 ohm load Not stated in the manual56 μC into a 100 ohm load Not stated in the manual	Tetanize	80 Hz ±10%	80 Hz	80 Hz
(u Coulombs) load  500 OHMS 33.5 ±10% Not stated in the manual Not stated in the manual	Maximum Current Density	0.132 mA/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
500 OHMS 33.5 ±10% Not stated in the manual Not stated in the manual			56 μC into a 100 ohm load	56 μC into a 100 ohm load
2K OHMS 13.1 ±10% Not stated in the manual Not stated in the manual	· · · · · · · · · · · · · · · · · · ·	33.5 ±10%	Not stated in the manual	Not stated in the manual
	2K OHMS	13.1 ±10%	Not stated in the manual	Not stated in the manual

## SYS\*STIM <sup>®</sup> 208/208A, MODEL ME 208/208A 510(K) SUMMARY

K031017

10K OHMS	
Formula	

 $3.4 \pm 10\%$ 

Not stated in the manual

Not stated in the manual

Not stated in the manual Not stated in the manual

**Maximum Power Density** 

0.012 W/cm<sup>2</sup> @ 500 Ω

Not stated in the manual

Not stated in the manual

#### **Amplitude Modulation Options**

Surge
-------

Frequency

80 Hz ±10%

80 Hz

80 Hz

On Times

0.375 to 3.75 seconds ±10% 0.375 to 3.75 seconds 0.375 to 3.75 seconds ±10% 0.375 to 3.75 seconds

0.375 to 3.75 seconds 0.375 to 3.75 seconds

Off Times Recip

0.070 to 0.70 00

Frequency

80 Hz ±10%

80 Hz

80 Hz 0.375 to 3.75 seconds

On Times
Off Times

0.375 to 3.75 seconds  $\pm 10\%$  0.375 to 3.75 seconds 0.375 to 3.75 seconds  $\pm 10\%$  0.375 to 3.75 seconds

0.375 to 3.75 seconds

### **Modulation Options**

a) May Be Selected Independently Or N/A

N/A

N/A

Together
b) Simultaneously For

Each Channel Pair

N/A

N/A

N/A

c) Independent Controls For Each Channel

N/A

N/A

N/A

Note 1: The Current density and Power density have been calculated using Average Current.

Average Current = (Pulse Width / Pulse Frequency) \* Peak Current

where Pulse Width and Pulse Frequency is in microseconds

Pulse Width = 182 microseconds @ 500 Ohms, Observed on CRO Pulse Frequency = 12500 microseconds (80 Hz - Maximum Frequency)

equation for maximum phase

charge

Current = ( Output Voltage / 500 Ohms)

Phase Charge = Pulse Width x Current (peak to peak)

equation for maximum current

density

Current Density = (Pulse On period / Total Pulse period) x (Voltage /

resistance)

equation for Power Density

Power Density = Current Density x Output Voltage

#### DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

## MAY 3 0 2003

Mr. Robert E. Fleming Director, QA/RA Official Correspondent Mettler Electronics Corp. 1333 South Claudina Street Anaheim, California 92805

Re: K031017

Trade/Device Name: Sys\*Stim® 208 and 208A Regulation Number: 21 CFR 882.5890, 890.5850

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief, Powered

muscle stimulator

Regulatory Class: II Product Code: IPF, GZJ Dated: March 28, 2003 Received: March 31, 2003

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

Attachment 1b

Page of
510(k) Number (if known): <u>K031017</u>
Device Name: Sys*Stim 208 (ME208)
Indications For Use:
<ol> <li>Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain</li> <li>Temporary relaxation of muscle spasm</li> <li>Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles</li> <li>Increasing local blood circulation</li> <li>Prevention or retardation of disuse atrophy</li> <li>Muscle re-education</li> <li>Maintaining or increasing range of motion</li> </ol>
(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrent of CDRH Office of Device Evaluation (ODE)  (Division Sign-Off)  Division of General, Restorative and Neurological Devices  Prescription Use

Attachment 1b
Page of
510(k) Number (if known): K031017
Device Name: Sys*Stim 208A (ME208A)
Indications For Use:
<ol> <li>Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain</li> <li>Temporary relaxation of muscle spasm</li> <li>Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles</li> <li>Increasing local blood circulation</li> <li>Prevention or retardation of disuse atrophy</li> <li>Muscle re-education</li> <li>Maintaining or increasing range of motion</li> </ol>
(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)  Concurrent of CDRI Office of Device Evaluation (ODI)
(Division Sign-Off) Division of General, Restorative and Neurological Devices

Prescription Use / (Per 21 CFR 801.109) 510(k) Number K03 10 17
Over-The-Counter Use\_